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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,193	01/25/2002	Hyun Hwan Lee	1544.03	2887
29338	7590	11/20/2003	EXAMINER	
PARK & SUTTON LLP 3255 WILSHIRE BLVD SUITE 1110 LOS ANGELES, CA 90010			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/048,193

Applicant(s)

LEE ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Claims 1-6 are indefinite because of the use of the term “phLf-8 2”, “pBacLf 3”, “pBacPAK6 4”, “Sf9 5” or “Sf-Lf 6”. The term “phLf-8 2”, “pBacLf 3”, “pBacPAK6 4”, “Sf9 5” or “Sf-Lf 6” renders the claim indefinite, it is not clear whether the number at the end of the term is part of terminology or is an identification number for the item. Claims 1, 3 and 4 are also indefinite because of the use of the term “pBacLf 3 modified to permit the regulation of a lactoferrin gene by a polyhedrin promoter in a vector pBacPAK” and “a help vector pBacPAK6 4.....producing a recombinant insect virus from said recombinant insect cell”. The cited term renders the claim indefinite, it is not clear how pBacLf 3 is modified, from where the lactoferrin gene or the polyhedrin promoter is originated, whether pBacPAK is transfer vector 1, what is the help vector pBacPAK6 4, and how the recombinant insect virus is produced since the claim does not indicate the virus DNA being introduced into insect cell. Claims 1-3 are also indefinite as to how human lactoferrin is produced in step (c). Claims 2, 5 and 6 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

3. Claims 5 and 6 are indefinite as to “A biological verification method for a recombinant human lactoferrin”, it is not clear how the recombinant lactoferrin is verified as a human lactoferrin since the method only recites measuring the anti-bacterial activity of the protein. Claims 5 and 6 are also indefinite because the claim lacks an essential step, the outcome of the process, e.g., verifying the protein as recombinant human lactoferrin.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note that patentability of the product by process resides in the product, see MPEP 2113.

Therefore, the product prepared by biochemical purification or recombinant technique anticipates the same product produced by recombinant means using different clones. In the instant case, the human lactoferrin indicated in the reference is not distinguishable from the recombinant human lactoferrin of the claimed invention.

4. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Salmon *et al.* (Protein Expression and Purification 9, 203-210 (1997)).

Salmon *et al.* teach a human recombinant lactoferrin is produced in baculovirus-infected Sf9 cells (pages 204 and 206; claim 3).

5. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Miehke *et al.* (J. Clinical Microbiology, 34, 2593-2594 (1996)).

Michlke *et al.* disclose a method of measuring anti-bacterial activity of recombinant human lactoferrin (rhLF) against *Helicobacter pylori* by mixing various concentrations of rhLF with a suspension of *Helicobacter pylori* and measuring the bacterial growth of 13 *Helicobacter pylori* strains (page 2593, Table 1; claim 5).

6. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold *et al.* (Infection and Immunity 28, 893-898 (1980)).

Arnold *et al.* teach determination of bactericidal activity of human lactoferrin against a variety of microorganism including non-enteropathogenic isolate of *E. coli* (claim 6) by incubating samples of microorganism cells with saline, saturated lactoferrin or apolactoferrin at different concentrations, and measuring the colony counts of various microorganisms (page 894, Table 1; claim 5).

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Chih-Min Kam, Ph. D.
Patent Examiner

CMK

November 11, 2003

Christopher S. F. Low

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SUPERVISORY PATENT EXAMINER
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